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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,018	02/25/2005	Francois Poulin	15228-15US AD/mb	2821
20/988 7590 03/11/2010 OGILVY RENAULT LLP 1, Place Ville Marie SUITE 2500 MONTREAL, QC H3B 1R1 CANADA				
EXAMINER HENSON, DEVIN B				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,018

Applicant(s)

POULIN ET AL.

Examiner

DEVIN HENSON

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- 7) ☐ Paper No(s)/Mail Date 2/25/05

DETAILED ACTION

In response to the amendment filed on 2/25/2005, amended claims 4-8 and 10-12, original claims 1-3, 9, and 14-24, and cancelled claims 13, 25 and 26 are acknowledged. Therefore, claims 1-12 and 14-24 are currently pending.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/405703, filed 8/26/02. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and

(a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahay et al. (US Patent No. 5,824,085).

Regarding claim 1, Sahay et al. discloses an apparatus for planning a surgery, the apparatus comprising:

a display (102) for an image representing a patient's anatomy (see col. 9, lines 25-29);

a database of virtual implants (216) from which a user selects (see col. 8, lines 38-47);

a tool (110) for said user to manipulate in order to select said virtual implants from said database and place said virtual implants in said image at desired locations (see col. 9, lines 31-34); and

a positioning module adapted to calculating a position of a first of said virtual implants with respect to a second of said virtual implants and allow said user to align

said first and second virtual implants with respect to each other (see col. 11, lines 52-56 and col. 13, lines 30-33), adapted to generating relative position data as a function of said calculated position, and adapted to sending said relative position data to said display (see col. 14, lines 13-22).

Regarding claim 2, Sahay et al. discloses said calculating a position comprises determining how well said virtual implants fit along a curve representing an interconnecting member for said virtual implants (see col. 12, lines 53-60 and col. 13, lines 30-33). The examiner notes that the fit criteria define the curve for the virtual implants.

Regarding claim 4, Sahay et al. discloses said tool allows said user to input a desired relative position of said first virtual implant with respect to said second virtual implant (see col. 5, lines 21-33 and col. 13, lines 30-33), and said positioning module updates a position of at least one of said first virtual implant and said second virtual implant as a function of said desired relative position (see col. 14, lines 13-22).

Regarding claim 5, Sahay et al. discloses said tool allows said user to group together a plurality of virtual implants and input a desired relative position of said plurality of virtual implants with respect to another of said virtual implants (see col. 5, lines 21-33 and col. 13, lines 8-10 and 30-33), and said positioning module updates a position of at least one of said plurality of virtual implants and said another virtual implant as a function of said desired relative position (see col. 14, lines 13-22).

Regarding claim 6, Sahay et al. discloses said positioning module updates a position of a first virtual implant after said second virtual implant has been placed by

said user at said desired location as a function of a predetermined relative position criteria (see col. 5, lines 21-33 and col. 13, lines 30-33).

Regarding claim 7, Sahay et al. discloses said relative position data is graphically represented by said display (see col. 5, lines 21-33 and col. 14, lines 13-22). The examiner notes that the computer-generated image of the relative position data is a "graphical representation" on the display.

Regarding claim 8, Sahay et al. discloses said display is for displaying a fluoroscopic image representing said patient's anatomy (see col. 7, lines 13-17).

Regarding claim 9, Sahay et al. discloses said display updates said image every time a new fluoroscopic image is taken of said patient's anatomy (see col. 5, lines 21-33 and col. 14, lines 13-22).

Regarding claim 10, Sahay et al. discloses said relative position data comprises an entry point of said virtual implants in said anatomy (see col. 5, lines 21-24 and col. 11, lines 52-56). The examiner notes that determining a reasonable initial location for placement of the prosthesis inherently requires determining an entry point.

Regarding claim 11, Sahay et al. discloses said relative position data comprises orientation of said virtual implants in said anatomy (see col. 5, lines 21-24 and col. 11, lines 52-56). The examiner notes that determining prosthesis size and shape along with placement location inherently requires properly orienting the virtual implant.

Regarding claim 12, Sahay et al. discloses Sahay et al. discloses said relative position data comprises depth information of said virtual implants in said anatomy (see

col. 5, lines 21-24 and col. 11, lines 52-56). The examiner notes that determining prosthesis size and shape inherently requires depth information of the virtual implants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 14-18, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahay et al. (US Patent No. 5,824,085) in view of Foley et al. (US Patent No. 6,434,415 B1).

Regarding claim 3, it is noted that Sahay et al. is directed towards long bone orthopaedic surgery and does not specifically teach a spinal surgery procedure where the virtual implants are two spinal implants. However, Foley et al. discloses said surgery is a spinal surgery (see col. 7, lines 45-49), said virtual implants are at least two spinal implants (10, 20, 30), and said positioning module is for aligning said at least two spinal implants along a curve representing an interconnecting member for said spinal implants (see col. 2, lines 45-48 and col. 5, lines 32-58). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the apparatus of Sahay et al. to make the virtual implants at least two spinal implants for a spinal surgery procedure, as disclosed in Foley et al., because spinal implant insertion is a common and well-known surgical procedure utilizing image-guided surgical methods (see Foley et al.: col. 7, lines 45-52).

Regarding claim 14, Sahay et al. discloses a method for placing at least two implants during a surgery using a computer assisted surgery system, the method comprising:

- providing an image representing a patient's anatomy (see col. 9, lines 25-29);
- determining a desired curve along which said at least two implants are to be placed and representing said curve on said image (see col. 12, lines 53-60 and col. 13, lines 8-10 and 30-33), said desired curve corresponding to an interconnecting member

for said at least two implants; The examiner notes that the fit criteria define the curve for the virtual implants as well as the relationship between each implant.

selecting at least two virtual implants from a database of virtual implants to correspond to said at least two implants (see col. 8, lines 38-47 and col. 13, lines 8-10);

placing said at least two virtual implants on said desired curve in said image by aligning said at least two virtual implants with said desired curve while taking into account a position of a preceding virtual implant to place a subsequent virtual implant (see col. 5, lines 21-33 and col. 13, lines 8-10 and 30-33); and

placing said at least two implants according to said virtual implants in said image using said computer assisted surgery system (see col. 9, lines 41-48 and col. 13, lines 8-10). It is noted that Sahay et al. is directed towards long bone orthopaedic surgery and does not specifically teach a spinal surgery procedure where the virtual implants are two spinal implants. However, Foley et al. discloses at least two spinal implants (10, 20, 30). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the apparatus of Sahay et al. to make the virtual implants at least two spinal implants for a spinal surgery procedure, as disclosed in Foley et al., because spinal implant insertion is a common and well-known surgical procedure utilizing image-guided surgical methods (see Foley et al.: col. 7, lines 45-52).

Regarding claim 15, Sahay et al. discloses said placing said at least two virtual implants comprises using lines to join together said virtual implants and align them on said image representing a patient's anatomy (see Figures 20A-D and col. 12, lines 53-

60 and col. 13, lines 8-10 and 30-33). The examiner notes that the fit criteria define the orientation and alignment between each implant.

Regarding claim 16, Sahay et al. discloses said placing said at least two virtual implants comprises calculating a location for said subsequent virtual implant based on a location of said preceding virtual implant (see col. 5, lines 21-33 and col. 13, lines 30-33 and col. 14, lines 13-22). The examiner notes that the fit criteria define the orientation and alignment between each implant.

Regarding claim 17, Sahay et al. discloses said selecting said at least two virtual implants comprises selecting said subsequent virtual implant having one of a position and a shape based on constraints imposed by said preceding virtual implant (see col. 11, lines 51-56 and col. 13, lines 30-33 and col. 14, lines 13-22). The examiner notes that the fit criteria define the orientation and alignment between each implant and determine size, shape, and location for each implant relative to the other implants.

Regarding claim 18, Sahay et al. discloses said placing said at least two virtual implants comprises re-adjusting a position of said preceding virtual implant to better position said subsequent virtual implant in order to achieve an optimal alignment of all of said virtual implants (see col. 12, lines 53-60 and col. 13, lines 30-33 and col. 14, lines 13-22). The examiner notes that the fit criteria define the orientation and alignment between each implant and determine size, shape, and location for each implant relative to the other implants.

Regarding claim 21, Sahay et al. discloses said placing said at least two virtual implants comprises determining at least one of an entry point, a depth, and an

orientation of each of said virtual implants on said anatomy (see col. 5, lines 21-24 and col. 11, lines 52-56). The examiner notes that determining prosthesis size and shape along with placement location inherently requires determining an entry point, properly orienting the virtual implants, and gathering depth information of the virtual implants.

Regarding claim 22, Sahay et al. discloses said placing at least two virtual implants comprises placing according to predetermined relative position criteria (see col. 12, lines 53-60 and col. 13, lines 30-33).

Regarding claim 23, Sahay et al. discloses said providing an image comprises providing a fluoroscopic image ((see col. 7, lines 13-17).

Regarding claim 24, Sahay et al. discloses said placing said at least two implants comprises updating said fluoroscopic image after each of said at least two implants has been placed (see col. 9, lines 41-48 and col. 13, lines 8-10 and 30-33 and col. 14, lines 13-22).

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahay et al. (US Patent No. 5,824,085) and Foley et al. (US Patent No. 6,434,415 B1, hereinafter referred to as "Foley et al. '415") in view of Foley et al. (US Patent No. 6,226,548 B1, hereinafter referred to as "Foley et al. '548").

Regarding claim 19, Sahay et al. discloses said at least two virtual implants are three virtual implants (see col. 13, lines 8-10). It is noted that Sahay et al. does not specifically teach the interconnecting member is a rod to interconnect three spinal implants. However, Foley et al. '548 discloses the interconnecting member is a rod (360) to interconnect three spinal implants (see col. 1, lines 29-34 and col. 10, lines 43-

46). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Sahay et al. to have an interconnecting member that is a rod for connecting three spinal implants, as disclosed in Foley et al. '548, so as to stabilize the three spinal implants (see Foley et al. '548: col. 10, lines 43-46).

Regarding claim 20, Sahay et al. discloses said placing at least two virtual implants comprises grouping together two of said three virtual implants (see col. 13, lines 8-10 and 30-33) and positioning said two virtual implants according to a desired relative position to at least one other virtual implant (see col. 5, lines 21-33 and col. 11, lines 52-56 and col. 12, lines 53-60 and col. 14, lines 13-22).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Noble et al. (US Publication No. 2004/0030245 A1) discloses a computer-based training method for surgical procedures that provides a computer simulation of a surgical operation to establish geometric, spatial, kinematic, and kinetic parameters to guide the surgeon during the surgical operation.

Reinert et al. (US Publication No. 2004/0044295 A1) discloses a computer system for computer-assisted surgery that displays virtual images of surgical instruments and implants during implant site planning, implant site preparation, and implant installation.

Williamson, Jr. (US Patent No. 5,769,092) discloses a computer-aided system to replace a bone prosthesis that receives bone image data and defines bounding

contours to accommodate removal of a first bone prosthesis and implantation of a second bone prosthesis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVIN HENSON whose telephone number is (571)270-5340. The examiner can normally be reached on M-TH 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. H./
Examiner, Art Unit 3736
3/10/10

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

